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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,301	08/31/2001	Maria A. Glucksmann	381552003600	2014

7590

08/29/2003

MILLENNIUM PHARMACEUTICALS INC
INTELLECTUAL PROPERTY GROUP
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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/29/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,301

Applicant(s)

GLUCKSMANN ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002 and 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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Applicant's election without traverse of Group I, claims 1-3 and 6-8 in Paper No. 11 is acknowledged.

Claims 4-5 and 9-24, and claim 7 limited to detecting a polypeptide are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

The examiner mistakenly crossed through the reference listed on the PTO-1449 because no reference were found in the application folder and later found the computer disk containing the references. If applicant will send another PTO-1449 the examiner will sign it.

The disclosure is objected to because of the following informalities:

The specification is confusing in the recitation of the blank lines, e.g. on page 2, lines 20, 23 and 27; page 3, line 22; page 9, line 10, etc.

The specification contains embedded hyperlinks and/or other forms of browser-executable code on e.g. page 5, lines 17 and 25; page 6, lines 2, 10, 17, 24; page 7, lines 1, 7, 13, 20; page 12, lines 14, 24; page 13, lines 2, 11, 20, 23; page 14, lines 6, 14, 21, 31, etc. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant specification teaches that SEQ ID NO:1 and 3 encode a human hydroxylase of the cytochrome P450 family and that SEQ ID NO:2 is the polypeptide encoded. However, the polypeptide has not been isolated and assayed and the identity is only supposition, absent convincing proof to the contrary. The data shown in Fig. 3-13 is a comparison with some consensus protein, the significance is not known.

Claims 1-3 and 6-8 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1, 3 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 6 recite "at least 15 nucleotides of the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:3..." and "at least 15 contiguous amino acids of SEQ ID NO:2". This reads on molecules that consist of nucleotides from

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anything whatsoever having 15 nucleotides or that encode 15 amino acids since the word "comprises" is used. The molecule could be from a completely unrelated gene as long as it met these characteristics. Therefore one of ordinary skill in the art would not know how to make and/or use the claimed invention.

Claims 1 and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are confusing and indefinite in the recitation of the blank lines.

Claim 6 is indefinite in the recitation of "hybridizes" on line 13. The conditions of hybridization are not given. Essentially any nucleic acid will hybridize to another if the hybridization conditions are low enough.

Claims 7 and 8 are confusing in that it contains embodiments not elected for prosecution, namely "[a] method for detecting the presence of...a polypeptide encoded by the nucleic acid molecule, comprising: a) contacting the sample with a compound which...binds to the polypeptide encoded by the nucleic acid molecule; and b) determining whether the compound...binds to the polypeptide in the sample" and "[a] kit comprising a compound which...binds to a polypeptide encoded by the nucleic acid molecule...", respectively.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Birren, et al. (U). The instant reference teaches a nucleotide sequence that has at least 15 nucleotides of SEQ ID NO:1 and 3.


Claims 3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren, et al. (U). The instant reference is characterizes *supra*. It would have been obvious and well within the skill level of one of ordinary skill in the art to place the nucleic acid into a host cell, use the host cell to produce a polypeptide and to detect the presence of the nucleic acid, absent unexpected results. The motivation would have been to further study the nucleic acid and polypeptide it produced and the detect the presence of the nucleic acid in various samples to ascertain whether it is present.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
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Patterson
August 26, 2003